DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: ReFacto
Docket No. 01E-0097

#23

The Honorable James. E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

DEC 10 2002

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 4,868,112 filed by the Genetics Institute, Inc. under 35 U.S.C. § 156. The patent claims the human biological product ReFacto (novel procoagulant proteins), product license application BLA 98-0137.

In the February 5, 2002, issue of the Federal Register (67 Fed. Reg. 5289), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before August 5, 2002, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Steven P. O'Connor
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